

USSN 09/285,632  
Page 2

### **REMARKS**

Claims 22-27, 41-42, 46-48, 50-56 and 58 were pending and claims 57, 59-75 were previously withdrawn. Claims 76 and 77 have been added by this amendment. All prior claims have been rejected. Claim 22 has been amended. Claim 22 is amended to recited that the modified starch has improved water solubility as supported at least at page 4, lines 10-11, and to recite that the coating is soluble. New claim 76 recites a coating wherein the modified starch and plasticizer are dispersible in cold water and the modified cellulose is dispersible at 60 C, as supported in the Examples, for instance, Example 1, page 8, lines 15 -21. Applicants contend the instant amendment places the claims in form for allowance, does not raise new issues, and does not add new matter.

### **35 CFR §112 REJECTION**

All claims are said to be rejected because the specification does not provide support for "the coating does not contain a water insoluble polymer". Applicant believes this rejection to be in error with respect to claim 57, which does not recite this limitation, and respectfully requests that this rejection be withdrawn with respect to claim 57. The limitation has been maintain in claim 22 because the language is supported at least on: page 5, lines 24-33, teaching that unmodified starch and cellulose are not soluble; page 5, lines 29-33 to page 6, lines 1-37 teaching the use of only modified starches and modified cellulose and that modified starches and cellulose materials are soluble; and in Examples describing dispersion of the starch in cold water thereby showing that the starch is not insoluble. Additionally, page 5, lines 30-32 state that the combined ingredients provide a coating that has "good solubility". Page 6, lines 1-4 state that "blends of modified starch and a secondary polymer such as modified cellulose have an advantage in that, for example, they combine the superior film-forming properties of modified cellulose, with the greater solubility and barrier properties of modified starch." Independent claim 22 and added independent claim 77 are limited to coatings of modified starches and celluloses. In addition, Applicants have amended claim 22 to add that the modified starch has improved solubility as supported by the language cited above.

### **35 CFR §103 REJECTION**

Claims 22-26, 41, -42, 46-48, 50-54, and 58 are rejected under 35 U.S.C. §103(a) as being unpatentable over Oshlack et al., (U.S. Pat. No. 5,639,476

With respect to this rejection under 35 U.S.C. §102(b) the Examiner states,

GGC530-2

USSN 09/285,632  
Page 3

"Oshlack teaches controlled release (emphasis added) coating composition comprising zein, water soluble plasticizer, and mixture of rate-controlling agents, including water soluble hydrophilic polymers and modified starch (columns 4-5, and 7-9).....The examiner notes that the reference briefly mentions the combination of hydrophobic acrylic polymer as a pore-former, with no further indication or explanation as to its function. However, omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. app. & Inter. 1989). ...."Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation omit the hydrophilic polymer where the function attributed to such polymer is not desired or required.

Applicants respectfully, but strongly dispute the Examiner's characterization of Oshlack et al. Oshlack does not "briefly mention" use of hydrophobic acrylic polymer. Hydrophobic acrylic polymers are essential elements of all embodiments, as pointed out by Applicants previously, and Oshlack's hydrophobic acrylic polymers are not identified by Oshlack as "pore-formers". See Col. 7, lines 35-38. See hydrophobic acrylic polymer listed as the primary ingredient in every object and embodiment set out in cols. 3 and 4, specifically, col. 3, lines 8, 19, 25, 35, 48 and col. 4, lines 13, 40, and 63.

The Examiner has admitted that Oshlack et al. is a controlled release coating. The controlled release is accomplished with an aqueous dispersion of a hydrophobic acrylic polymer, polymers that permit some release, and optional pore formers, which enhance release. It is clear to Applicants that a controlled release coating, by definition, cannot rapidly dissolve in use because such a coating could not provide "controlled release" of anything. Controlled release formulations must have a component(s) that is insoluble or at least very resistant to water (Oshlack's hydrophobic acrylic polymer). "Hydrophobic" is defined as "not readily wettable by water" in Webster's Third New International Dictionary, by Merriam-Webster Inc. (1986). Hydrophobic substances are not referred to in the industry as water soluble substances, but rather as water insoluble substances.

Controlled release coatings, including those taught by Oshlack et al., also may have soluble components added to control the rate of release. Amounts and types of soluble components will vary depending upon the desired rate of release. Oshlack's release rates are said to be, for example, 0 to 42.5% release after 1 hour, 5-60% release after 4 hours, 15-75% release after 8 hours (Col. 4, lines 47-51). The Examiner is referred to the figures in Oshlack et al showing delayed release time curves. Oshlack

GGC530-2

USSN 09/285,632

Page 4

et al. uses optional soluble pore-formers, certainly not hydrophobic acrylic polymers, to regulate the release rate because the pore-formers are soluble. Polymers listed as pore-formers are stated to be "water-soluble hydrophilic polymers (Col. 10, line 46), not hydrophobic polymers as stated by the Examiner. All of Oshlack's pore formers are disclosed at Col. 10, lines 36-66 to Col. 11, line 41. Please see Col. 11, lines 42-46 for the teaching that "the amount of pore-former included in the controlled release coatings of the present invention may be from about 0.1% to about 80% by weight, relative to the combined weight of hydrophobic acrylic polymer (emphasis added) and pore-former." The use of only pore-formers as recited by the Examiner could not result in a time-release granule and Oshlack et al. do not teach or suggest a granule having only soluble pore former ingredients.

Applicants do not understand the Examiner's statement that it would "have been obvious for one of ordinary skill in the art to, by routine experimentation omit the hydrophilic polymer where the function attributed to such polymer is not desired or required". (page 5). Applicants have not omitted the hydrophilic polymer as applicants' polymers are soluble (read hydrophilic). If the Examiner meant to say that Applicants have omitted a hydrophobic polymer, the cases cited by the Examiner do not apply because such an omission would not result in a coating that is a controlled release coating. The cases cited by the Examiner concerned compositions that continued to provide the basic utility, function and purpose of the prior art compositions, i.e. both were anticorrosion epoxy resins (Ex parte Wu, 10 USPQ 2031 (1989), both were mobile fluid carrying units (In re Larson, 340 F.2d 965 (1965). In the instant case, elimination of the primary hydrophobic acrylic polymer ingredient does not result in a time release coating that could be used to delay release of a substance, and conversely, provision of all soluble ingredients characterized as pore formers by Oshlack et al. does not result in a time release coating.

Applicants' contend that all of the claims distinguish over Oshlack since all embodiments of Oshlack require a water insoluble polymer. Clearly there is no teaching in Oshlack et al. directed to a coating having only soluble modified starch, soluble modified cellulose, and a plasticizer wherein the coating does not contain a water insoluble polymer as recited in claim 22. Such a coating would consist only of Oshlack et al.'s optional pore formers and a plasticizer.

GGC530-2

USSN 09/285,632  
Page 5

All claims also are rejected under 35 USC §103(a) over Oshlack with the Examiner stating that:

Oshlack teaches a pharmaceutical formulation in the form of tablets, beads, seeds, or granules that can be coated with a coating composition comprising water-soluble hydrophilic polymer (column 10, lines 45-06), modified starch (column 11, lines 12-41), and plasticizer (column 12, lines 29 through column 14, lines 1-40). The Examiner notes that the reference teaches the use of hydrophobic acrylic polymer in certain preferred embodiments. However, applicant has not provided any comparative data showing that the present of the hydrophobic acrylic polymer would have a detrimental effect upon the desirability to obtain a useful coating composition. Hence it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation modify Oshlack's coating composition with the expectation of at least similar result, because Oshlack recognizes the properties of modified starch and cellulose in coating composition useful for the same purpose desired by the application, e.g. coating composition for cleansing agent, therapeutic active agent, fertilizing agent, or disinfecting agent.

Again, as pointed out above, the Examiner continues to ignore the clear fact that all of Oshlack's embodiments have a hydrophobic, insoluble, acrylic polymer as the starting material for a "controlled release" coating. Because Applicants do not teach or describe a "controlled release" coating, but rather teach that soluble coatings are desired, there was no reason for Applicants to provide data in the specification comparing its coatings to "controlled release" coatings. Nevertheless, Applicants present the data set out below showing the rapid solubility of Applicants' coatings, which can be compared to the delayed release coating data taught by Oshlack et al.

A Declaration of Mark S. Gebert is attached describing in detail the test summarized below. Dissolution of granules having the enzyme protease and a coating of equal parts of Pure Cote (modified starch) and methyl cellulose were placed in distilled water and stirred at room temperature. Aliquots were removed from the beaker at regular time intervals. The enzymatic activity of the aliquots was measured using a conventional kinetic based spectrophotometric assay. The presence of enzyme activity resulted in an increase in optical density (OD) and demonstrated rapid release of the enzyme. The amount of enzyme released was calculated from the OD values. The table below shows the amount of enzyme released in milligram units, and release leveled off by approximately 1 to 6 minutes when substantially all of the enzyme was released. Subsequent timed samples showed no significant change in OD. The table demonstrates that the coating is highly soluble and allowed release of substantially all of

GGC530-2

USSN 09/285,632

Page 6

the enzyme in less than 6 minutes, as opposed to the partial, and substantially delayed release of a relatively small amount of enzyme in Oshlack after, for instance 1 hour.

Adding hydrophobic acrylic polymer would result in loss of the rapid release.

Time in Seconds	Enzyme Released (mg)
0	0.0
15	0.0
30	1.4
45	4.9
60	6.0
90	6.2
120	6.3
180	6.4
240	6.6
300	6.3
360	6.8
420	6.3
480	6.2

In addition to the data presented above, Applicants' have attached product literature obtained from 2 web sites after a brief search. The information is highlighted and shows, as examples illustrative of the entire list, 3 of the modified starches listed on page 4 of Applicants' specification as soluble in cold water. A Declaration by Mark Gebert is attached hereto as Attachment A, detailing the experiments set out above.

A *prima facie* case of obviousness requires the Examiner to cite to a reference or a combination of references which (a) suggests or motivates one of skill in the art to modify the teachings of the reference(s) to yield the claimed invention, (b) discloses the elements of the claimed invention, and (c) provides a reasonable expectation of success should the claimed invention be carried out. Failure to establish any one of these requirements precludes a finding of a *prima facie* case of obviousness and, without more, entitles Applicants to withdrawal of the rejection of the claims at issue. See e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990); *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988).

GGC530-2

USSN 09/285,632

Page 7

Applicants respectfully submit that the Examiner has failed to establish not just one, but all three requirements as discussed below.

It is axiomatic for establishing a *prima facie* case of obviousness that "all the claim limitations must be taught or suggested by the prior art."<sup>1</sup> MPEP § 2143.03, citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). However, the Examiner has not and cannot point to the limitations included within the present Claims. Unlike the presently claimed invention, Oshlack et al. do not provide a coating consisting of a soluble modified starch, including the recited modifications, a plasticizer and a modified secondary polymer, wherein the coating is not a delayed release coating or does not include a water insoluble polymer. Oshlack et al. only teach the use of a pore-former in combination with a hydrophobic acrylic polymer that is not soluble in order to provide a controlled release coating. It is impermissible within the framework of section 103 to pick and choose from any reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art; and it is particularly impermissible to pick and choose only optional ingredients, with complete disregard for the primary component of the invention, and combine them in ways not suggested or taught by the reference. Thus, there are elements of the presently claimed invention, which are lacking from the Oshlack et al. reference.

A second essential requirement for a *prima facie* case of obviousness is whether a person skilled in the art would be motivated to modify the reference to arrive at the claimed invention.<sup>2</sup> *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988) and *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). In particular,

"the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990)

As the Oshlack et al. method addresses a different problem than that presently claimed, Applicants submit that there is no motivation to modify the teachings of the

---

GGC530-2

USSN 09/285,632

Page 8

Oshlack et al. to produce the presently claimed soluble coating. There is no motivation to select only optional ingredients and leave out the primary delayed release component - the hydrophobic acrylic polymer. Applicants respectfully submit that the Examiner is arguing that it would be obvious to try to modify the teachings of the Oshlack et al. reference to produce the presently claimed invention. This is an improper basis for obviousness. The "obvious to try" standard has been thoroughly discredited. Indeed, an obviousness rejection is inappropriate, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful" (quoting *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 [Fed. Cir. 1988], *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 10 USPQ2d 1843, 1845 [Fed. Cir. 1989]). Oshlack cites a great many pore-formers, it would be purely accidental to select the combinations claimed by Applicants, and there is no motivation in Oshlack to use only pore formers.

Finally, a fundamental requisite of establishing a *prima facie* case of obviousness is that there is a reasonable expectation of success in practicing the recited method steps or producing the claimed composition, without the use of the pending Application. Indeed,

"[t]he reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990)

The Examiner's has made only a singular statement with regard to this prong of a *prima facie* case of obviousness, specifically, that "it would have been obvious to one of ordinary skill, by routine experimentation" . . . to (1) omit the hydrophilic polymer or (2) modify Oshlack's coating composition with the expectation of at least similar result.

The reasonable expectation of success must be founded in the prior art, not Applicant's disclosure, and in view of the prior art's controlled release emphasis, no logical argument can be advanced in support of the cited reference's teaching of a reasonable expectation of success based on Oshlack et al. Certainly there is motivation to omit the hydrophilic polymer in Oshlack, since it is optional, but there is no motivation to omit hydrophobic polymer since it is an essential ingredient.

In view of the above, Applicants respectfully submit that the Claims are unobvious and request that this rejection be withdrawn.

GGC530-2


USSN 09/285,632  
Page 9

**CONCLUSION**

Applicants have addressed each of the Examiner's rejections and respectfully request reconsideration of the present Claims. Indeed, Applicants respectfully request withdrawal of the rejections. Accordingly, Applicants further request that the claims be permitted to proceed to a speedy allowance.

Respectfully submitted,

Date: April 17, 2003

  
Janet Kaiser Castaneda  
Registration No. 33,228

Genencor International, Inc.  
925 Page Mill Road  
Palo Alto, CA 94304  
Tel: 650-846-4072  
Fax: 650-845-6504

GGC530-2